

### **Remarks**

This Amendment is in response to the Office Action dated **April 3, 2007**. In the Office Action, claims 2-14, 16-19 and 21-24 were objected to; claims 1, 2, 8 and 10 were rejected under 35 USC 102(b) as being anticipated by Barath (5,616,149); claims 11-14 were rejected under 35 USC 103(a) as being unpatentable over Barath (5,616,149); claims 3-4 were rejected under 35 USC 103(a) as being unpatentable over Barath (5,616,149) in view of Vigil (5,320,634); claims 5-7, 15-16, 18-22 and 24 were rejected under 35 USC 103(a) as being unpatentable over Barath (5,616,149) in view of Shiber (6,730,105); and claims 9, 17 and 23 were rejected under 35 USC 103(a) as being unpatentable over Barath (5,616,149) in view of Shiber (6,730,105) further in view of Vigil (5,320,634).

The following comments are presented in the same order, with section headings, as the Office Action.

### **Information Disclosures Statement**

In the Office Action, the information disclosure statements of April 14, 2004 and March 25, 2004 were acknowledged. Applicants acknowledge that the information disclosure statements were being considered by the Examiner.

### **Claim Objections**

In the Office Action, claims 2-14, 16-19 and 21-24 are objected to because of informalities. Specifically, line 1 of the claims read "A cutting balloon" and should be changed to "The cutting balloon." Applicants have amended the claims as requested. Applicants request withdrawal of the objection.

### **35 USC 102**

In the Office Action, claims 1, 2, 8, and 10 are rejected under 35 USC 102(b) as being anticipated by Barath (5,616,149). Applicants assert that Barath does not teach or suggest all the elements recited in instant independent claim 1, from which claims 2, 8 and 10 depend.

The Office Action asserts that Barath teaches or suggests:

a radially compressible sheath 17 mounted on said balloon along the length of said incising element and extending radially from said balloon and beyond said surface feature when said balloon is in the first configuration to protect said surface feature during transit to the treatment site, said sheath being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated into the second inflation (Figures 11-13; col. 5, lines 14-36).

First, Applicants note that Fig. 11 is a longitudinal view of the third embodiment, which is shown in the cross-sections of Figs. 9 and 10, while Figs. 12 and 13 are cross-sections of a fourth embodiment. The third embodiment is discussed in col. 5, lines 1-19 and the fourth embodiment is discussed in col. 5, lines 20-36.

Applicants assert that Barath does not teach “said sheath being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated into the second configuration,” as recited in instant independent claim 1 and as shown, for example in Figs. 3 and 4, provided below. In Fig. 3 of the instant application, the sheath 52a,b extends radially from the balloon and beyond the cutting edge 48 of the blade 44. When the sheath 52a,b is radially compressed, as shown in Fig. 4 of the instant application, the cutting edge 48 of the blade 44 is exposed.

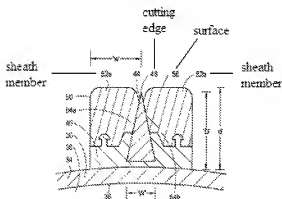


Fig. 3

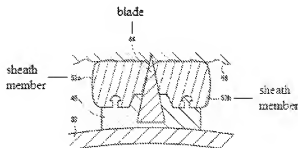


Fig. 4

In contrast, the sheath 17 of Barath has longitudinal grooves (18) that “open up” or get wider upon inflation of the balloon, as shown in annotated Figs. 12 and 13 provided below where the balloon is in a deflated state and an inflated state respectively.

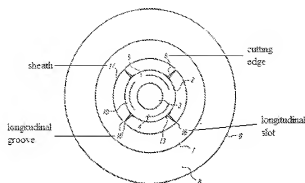


FIG. 12

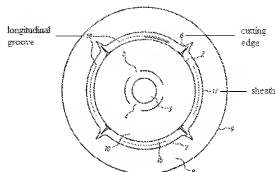


FIG. 13

Note that the width of the longitudinal slot 16 between the ends of the longitudinal grooves 18 is very narrow when the balloon 2 is in a deflated state (see Fig. 12). In contrast, the width of the longitudinal slot 16 between the ends of the longitudinal grooves 18 increases when the balloon 2 is in an inflated state (see Fig. 13). Inflation of the balloon causes the width of the longitudinal slot 16 to increase or “open up” which allows “the cutting edges (6) to penetrate into the vessel wall (7,8)” (col. 5, lines 31-33). Thus, the sheath 17 in Barath is not radially compressed to expose the cutting edges 6, contrary to instant independent claim 1.

For at least this reason, Applicants request withdrawal of the rejection and assert that claims 1, 2, 8, and 10 are in condition for allowance.

### 35 USC 103 – Barath

In the Office Action, claims 11-14 were rejected under 35 USC 103(a) as being unpatentable over Barath (5,616,149). As discussed above, Barath does not teach or suggest all the elements of independent claim 1, from which claims 11-14 depend. For at least this reason, Barath does not render claims 11-14 obvious. Applicants request withdrawal of the rejection and assert that claims 11-14 are in condition for allowance.

**35 USC 103 – Barath in view of Vigil**

In the Office Action, claims 3-4 were rejected under 35 USC 103(a) as being unpatentable over Barath (5,616,149) in view of Vigil (5,320,634). As discussed above, Barath does not teach or suggest all the elements of independent claim 1, from which claims 3-4 depend. The addition of Vigil, which is asserted to teach an incising element being partially encapsulated in said mounting pad, does nothing to address the failure of Barath to teach or suggest all the elements of independent claim 1. For at least this reason, Applicants request withdrawal of the rejection and assert that claims 3-4 are in condition for allowance.

**35 USC 103 – Barath in view of Shiber**

In the Office Action, claims 5-7, 15-16, 18-22 and 24 were rejected under 35 USC 103(a) as being unpatentable over Barath (5,616,149) in view of Shiber (6,730,105).

**Combination of Barath and Shiber does not teach or suggest all the elements of independent claim 1, from which claims 5-7 depend**

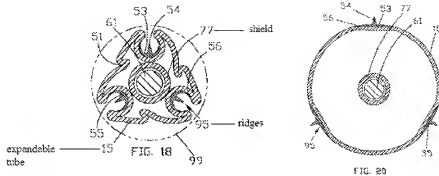
Independent claim 1 recites “an elongated balloon ... and a radially compressible sheath ...positioned for radial compression ... to expose said surface feature.”

As discussed above, Barath does not teach or suggest all the elements of independent claim 1. The Office Action asserts that Shiber teaches a pair of sheath members (upper surface of element 15), with each sheath member made of a flexible material to radially compress to expose the cutting edge, citing Figure 18; col. 6, lines 8-21 of Shiber.

Applicants assert that Shiber teaches only a sheath 15 or only a balloon, but not a balloon and a sheath, as recited in instant independent claim 1. Furthermore, the sheath of Shiber is not “positioned for radial compression to expose said surface feature for tissue incision” as recited in independent claim 1.

For reference, annotated Fig. 18 of Shiber is provided below. Figure 18 is a cross-sectional view of a fifth embodiment that has “an enlarged clover leaf shaped expandable tube in its relaxed, deflated, position and ridges harbored in folds of the expandable tube, the ridges having retracted parting edges at their mid section” (col. 3 lines 50-54). In Fig. 20,

provided below, the expandable tube is inflated.



As shown in Fig. 18, if element 15 is the sheath, element 77 is the only element that could be a balloon. However, as shown in Fig. 20, in which the expandable tube 15 is inflated, element 77 is not expanded since its position in relation to guidewire 61 is the same in Fig. 20 as in Fig. 18. Applicants note that expansion of the expandable tube 15 exposes the parting edge 54, contrary to claim 1. For at least this reason Shiber does not teach or suggest either 1) an elongated balloon and an a radially compressible sheath or 2) a sheath being positioned for radial compression to expose said surface feature as recited in independent claim 1.

Therefore the combination of Barath and Shiber does not teach or suggest all the elements of claims 5-7, which depend upon claim 1.

**Combination of Barath and Shiber does not teach or suggest all the elements of independent claim 15, from which claims 16, 18-19 depend**

Independent claim 15 recites “a cutting balloon comprising an elongated balloon ... and a sheath ... having a pair of sheath members ... each sheath member ... positioned longitudinally on said balloon ... each of said sheath member made of a flexible material to radially compress between said tissue and said balloon to expose said cutting edge for tissue incision during an inflation of said balloon.”

As discussed above, Barath does not teach or suggest the sheath being positioned for radial compression to expose said surface feature, as recited in independent claim 15. As discussed above, Shiber does not teach or suggest either 1) an elongated balloon and an a radially compressible sheath or 2) a sheath being positioned for radial compression to expose

said surface feature as recited in independent claim 15.

For at least these reasons, the combination of Barath and Shiber does not teach or suggest all the elements of instant independent claim 15, from which claims 16, 18-19 depend.

**Combination of Barath and Shiber does not teach or suggest all the elements of independent claim 20, from which claims 21-22 and 24 depend**

Independent claim 20 recites “a balloon ... and a sheath ... said sheath having a pair of elongated sheath members with each sheath member ... shaped to expose a preselected portion of said cutting blade for tissue incision when said sheath members are radially compressed between said tissue and said balloon during an inflation of said balloon.”

As discussed above Barath does not teach or suggest a sheath being radially compressed between said tissue and said balloon during an inflation of said balloon to expose a preselected portion of said cutting blades, as recited in instant independent claim 20. As discussed above, Shiber does not teach or suggest either 1) an elongated balloon and an a radially compressible sheath or 2) a sheath being positioned for radial compression to expose said surface feature as recited in independent claim 20. Therefore for at least these reasons, the combination of Barath and Shiber does not teach or suggest all the elements of instant independent claim 20, from which claims 21-22 and 24 depend.

Applicants request withdrawal of the rejection and assert that claims 5-7, 15-16, 18-22 and 24 are in condition for allowance.

**35 USC 103 – Barath in view of Shiber and Vigil**

In the Office Action, claims 9, 17 and 23 were rejected under 35 USC 103(a) as being unpatentable over Barath (5,616,149) in view of Shiber (6,730,105) further in view of Vigil (5,320,634). As discussed above, the combination of Barath and Shiber does not teach or suggest all the elements of independent claim 1, from which claim 9 depends, or all the elements of independent claim 15, from which claim 17 depends, or all the elements of claim 20, from which claim 23 depends. The addition of Vigil, which is asserted to teach an incising element partially encapsulated in said mounting pad and said mounting pad being bonded to said balloon, does nothing to address the failure of the combination of Barath and Shiber to teach or suggest

all the elements of instant claims 9, 17 and 23.

Applicants request withdrawal of the rejection and assert that claims 9, 17 and 23 are in condition for allowance.

### **Conclusion**

Based on at least the above, Applicants respectfully submit that this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1-24 is requested.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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By: / Jennifer L. Buss /  
Jennifer L. Buss  
Registration No.: 57321

6640 Shady Oak Rd., Suite 400  
Eden Prairie, MN 55344  
Telephone: (952) 563-3000  
Facsimile: (952) 563-3001